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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR                  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|---------------------------------------|-------------------------|------------------|
| 09/775,046  | 02/01/2001  | Johannes Eduard Maria Antonius Debets | DX01073K                | 3164             |
| 28008   | 7590        | 10/14/2003                            | EXAMINER                |                  |
| DNAX RESEARCH, INC.<br>LEGAL DEPARTMENT<br>901 CALIFORNIA AVENUE<br>PALO ALTO, CA 94304 |             |                                       | ANDRES, JANET L         |                  |
|   |             |                                       | ART UNIT                | PAPER NUMBER     |
|   |             |                                       | 1646                    |                  |
|   |             |                                       | DATE MAILED: 10/14/2003 |                  |

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/775,046

Applicant(s)

ANTONIUS DEBETS ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 11 August 2003 is acknowledged. Claims 4-10 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 5 and 6 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained***

4. The rejection of claims 4-10 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained for reasons of record in the office action of paper no. 13.

Applicant argues that a nexus exists between the current invention and inflammation because IL-1 $\epsilon$  is expressed in psoriasis, because the receptor signals through NF $\kappa$ B, and because the receptor is expressed in epithelial cells, monocytes, and lungs.

Applicant's arguments have been fully considered but have not been found to be persuasive. It is agreed that IL-1 $\epsilon$  expression in psoriasis indicates that inhibiting it might affect psoriasis. However, the claims encompass proliferation, remodeling, all inflammatory response and mediators, and, in claim 4, all events in cell physiology. Upregulation in one condition would not be predictive of similar upregulation in all inflammatory conditions, which have different etiologies and different courses. Applicant has provided no guidance as to what other tissues might show such upregulation and thus what other inflammatory conditions might involve IL-1 $\epsilon$ . Further, there is no guidance as to what other events might be affected by IL-1 $\epsilon$

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/IL-1R6. NF $\kappa$ B signaling is involved in many events (Epstein, cited by Applicant, p. 1819, column 1); thus one of skill in the art would not, given a system that affects NF $\kappa$ B, be able to predict that the system was involved in inflammation, nor would one of skill in the art be able to predict what other events in cell physiology the system might affect. That the receptor is expressed in epithelial cells, monocytes, and lungs also does not provide sufficient guidance to predict that its function; as stated in the office action of paper no. 13, it is also expressed in epididymus, testes, and the cerebral cortex. What is provided is merely an invitation to the artisan to use the current invention, the interaction of IL-1 $\epsilon$  with IL-1R6 and subsequent effects on NF $\kappa$ B, as a starting point for further experimentation, not the invention itself.

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
October 9, 2003



LORRAINE SPECTOR  
PRIMARY EXAMINER